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EXAMINER
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ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/772,477	BURGMEIER ET AL.	
	Examiner	Art Unit	
	Michele Jacobson	1709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 26-43* is/are pending in the application.

4a) Of the above claim(s) *21-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 26-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/28/05, 5/27/05, 5/21/04*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claim 21-25, drawn to method of making a medical device, classified in class 264, subclass 211.

   II. Claims 1-20 and 26-43, drawn to a medical device product, classified in class 428, subclass 35.7.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process such as casting or compression molding a polymeric material in the form of a polymeric part.

3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Walter Steinkraus on 8/13/07 a provisional election was made with traverse to prosecute the invention of group II, claims 1-20 and 26-43. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21-25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 4, 6-7, 11-12, 15-16, 18-20, 26-27, 30-31, 34-36, 41-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 6, and 21-24 of U.S. Patent No. 7,128,956. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both recite catheter or dilatation balloons composed of the same polymers with a variable amount of nucleating agent disposed longitudinally along the length of the article.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 30-31 and 41 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Muni et al. U.S. Patent No. 5,316,706 (hereafter referred to as Muni).

3. Muni teaches a catheter that varies in polymer crystallinity longitudinally. (Col. 2, lines 41-45) Polymers used to produce the catheter include polyethylene terephthalate, polyester, copolyesters, polyamides, copolyamides, polyetheretherketone, polyolefins, polycarbonate, polyurethanes, and polyimides. (Col 4, lines 31-34) The crystalline structure of the extruded catheter is altered by a process of selectively cold crystallizing different regions of the catheter. The catheter recited can vary in crystallinity from one portion to another as well as over a plurality of zones. (Col. 4, lines 18-23)

4. Muni clearly anticipates the catheter with a varying degree of crystallinity recited in claims 30 and 31. The possible polymer materials used to form the catheter in Muni clearly anticipate the polymers recited in claim 41.

5. Claims 1-4, 6-7, 11-20, 26-27, 30-37 and 41-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al. U.S. Patent No. 7,128,956 (hereafter referred to as Wang).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

6. Wang teaches treating polymeric materials suitable for catheter construction with a nucleating agent. (Col. 3, lines 15-16) The catheter produced has crystallization modifier disposed within a pre-formed bend region to "provide an altered crystalline microstructure within at least a portion of the preformed bend". (Claim 1) Polymers used to form the catheter include Nylon, polyetheretherketone, polyimide, polyetherimide, polyether block amide, and polyamide. (Col. 9, lines 6-16) Nucleating agents used include inorganic and organic additives and polymers including talc, silica, kaolin, molybdenum disulfide, iron sulfide, titanium dioxide, sodium phenylphosphonate, sodium p-tert-butylbenzoate, monton wax, montanic ester salts, salts of monocarboxylic acids and polycarboxylic acids, ethylene and acrylic ester copolymers, fumeric acid polymers, ethylene, propylene, 1,4-hexadiene and norbornadiene. (Col 8, lines 1-10) The possible ratios of nucleating agent to polymer are recited to be in the range from about 0.5% to 99.5% by weight. (Col. 8, lines 36-38) The catheters produced are recited to be useful in cardiology, neurology, urology and gastroenterology and in a further embodiment balloon dilatation catheters are specifically recited. (Col 3, lines 64-65, Col. 8, lines 54-56). The outer tubular member of the balloon catheter is recited to be modified by the addition of nucleating agent in the same way as the generic catheter recited thus resulting in a balloon catheter with a region of enhanced nucleation in the body portion presumably tapering off through the cone portions to the unaltered waist portions. (Col. 9, lines 44-45)

7. Regarding claims 1, 3-4, 7, 12, 15-16, 26-27, and 30-31: The features of the catheter and balloon catheter recited by Wang clearly anticipate the medical device part, tubing segment and catheter balloon of variable crystallization and/or variable percent composition of nucleating agent recited in claims 1, 3-4, 7, 12, 15-16, 26-27, and 30-31.

8. Regarding claims 2 and 17: The percent weight range recited by Wang encompasses the percent weight of crystallization modifier ranges recited in claims 2 and 17.

9. Regarding claims 6, 20, 37 and 41-42: Wang anticipates the crystallizable base polymers recited by applicants in claims 6, 20, 37 and 41-42.

10. Regarding claims 11, 13-14, and 32-36: Wang anticipates the balloon catheter outer shaft portion with varying amounts of crystallization modifier recited in claim 11. The balloon catheter outer shaft wherein the crystallization enhancer is not present in at least one region of the catheter outer shaft recited in claims 13 and 14 is anticipated by the balloon catheter outer shaft recited by Wang since only the body portion is interpreted to be treated with nucleating agents. This interpretation extends to the anticipation of the invention in claims 32-36.

11. Regarding claims 18 and 19: The catheter recited by Wang is in one embodiment essentially a polymeric tubing segment. Since the amount of nucleating agent in the tubing cannot be assumed to precipitously drop to zero, there would be disposed on the tubing segment a third region of tapering nucleating agent percent composition that would differ from the percentage of nucleating agent in the untreated

regions of the tubing and the middle of the treated region of the tubing. (Claim 18) By this interpretation, it can also be said that the amount of nucleating agent varies substantially continuously along the length of the tubing. (Claim 19)

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 30, 41, and 43 rejected under 35 U.S.C. 103(a) as being obvious over Wang et al. U.S. Patent No. 7,128,956 as applied to claims 1-4, 6-7, 11-20, 26-27, 30-37 and 41-42 above, and further in view of Wang et al. U.S. Patent No. 6,284,333 (hereafter referred to as '333).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR

1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

14. Wang is silent regarding the use of liquid crystal polymers for the catheter material.

15. '333 teaches a medical device comprised of a melt blend product of at least two different thermoplastic polymers one of which being a liquid crystal polymer. (Col. 1, lines 45-50).

16. The motivation to combine Wang and '333 would have been "to impart higher strength and resistance to shrinkage to the base polymer materials" by adding liquid crystal polymer. (Col. 1, 54-56)

17. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have combined Wang with '333 in order to produce the invention as claimed in claims 30, 41, and 43.

18. Claims 1-4, 6-7, 11-20, 26-27, 30-37 and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muni et al. U.S. Patent No. 5,316,706 as

applied to claims 30-31 and 41 above, in view of nucleating agents disclosed by applicant, and in further view of Satchell et al. U.S. Patent No. 4,276,250 (hereafter referred to as Satchell).

19. Muni does not teach adding different amounts of nucleating agents to varying the crystallinity of a catheter in the longitudinal direction.

20. Table 3 of applicants' disclosure "provides citations to examples of nucleating agents for polymer materials which occur in the open literature" (prior art). As indicated by applicants' disclosure it is well known in the art to change the crystallinity of polymer substances by adding nucleating agents. Furthermore, applicants' specification discloses a plurality of nucleating agents that are well known in the art.

21. Satchell teaches extruding plastic tubing having axial sections of materials having different characteristics. (Col. 2, lines 42-46)

22. One of ordinary skill in the art would have recognized at the time the invention was made that it was desirable to vary the crystallinity of a catheter longitudinally as disclosed by Muni and that selective addition of a nucleating agent along the length of the catheter could be used to accomplish this. The motivation would have been to increase the number of different polymers that could be utilized for catheter production beyond just those that are cold crystallizable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have combined Muni with the plurality of nucleating agents that are well known in the art as recited in applicants' disclosure.

23. The motivation to combine Muni and applicants' disclosure with Satchell would have been that "In the bio-medical field it is frequently necessary to manufacture plastic tubing having axial sections of different physical and/or chemical characteristics. For example, in the manufacture of suction catheters which are designed to be inserted through a patient's mouth and esophagus and into his lungs, it is desirable to make the forward or distal end of the catheter tube relatively soft to minimize the risk of damage to the patient's esophagus and lungs during insertion, and to make the rear or proximal end of the tube relatively stiff to facilitate insertion and positioning of the tube." (Satchell, Col. 1, lines 14-24)

24. Utilizing the extrusion method of Satchell to extrude alternating sections of polymer with and without nucleating agent added would produce a catheter with the same desirable characteristics as that disclosed by Muni. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have combined Muni, applicants' disclosure and Satchell to produce the invention as claimed.

25. Regarding claims 1, 3-4, 7, 12, 15-16, 26-27, and 30-31: It would have been obvious to one having ordinary skill in the art at the time the invention was made to have produced a medical device part, tubing segment or catheter balloon of variable crystallization and/or variable percent composition of nucleating agent as recited in claims 1, 3-4, 7, 12, 15-16, 26-27, and 30-31.

26. Regarding claims 2 and 17: It would have been obvious to one having ordinary skill in the art at the time the invention was made to have optimized the amount

crystallization modifier added to the polymer and to vary the amount according the degree of crystallinity desired.

27. Regarding claims 6, 20, 37 and 41-42: Muni teaches a number of the crystallizable base polymers recited in claims 6, 20, 37 and 41-42. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized any crystallizable polymer material suitable for medical applications as claimed in claims 6, 20, 37 and 41-42.

28. Regarding claims 11, 13-14, and 32-36: It would have been obvious to one having ordinary skill in the art at the time the invention was made to have produced a balloon catheter with varying amounts of crystallization modifier as recited in claim 11. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have produced a balloon catheter with increased crystallization modifier in the body portion and none on the ends in order the optimize the flexibility profile of the catheter. (Claims 13-14 and 32-36)

29. Regarding claims 18 and 19: It would have been obvious to one having ordinary skill in the art at the time the invention was made to have varied the amount of crystallization modifier along the length of the catheter tubing depending on the application. One of ordinary skill in the art would have recognize that in some applications it is desirable to have the proximal end of the tubing to be much more rigid than the body portion for guiding purposes and to have the distal section of the tubing be much more flexible to prevent damage to the surrounding tissue.

30. Claims 1, 7-10, 26, 28-29, 30,34 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muni et al. U.S. Patent No. 5,316,706 as applied to claims 30-31 and 41 above, in view Sahatjian U.S. Patent No. 5,306,246 (hereafter referred to as Sahatjian), and in further view of Satchell et al. U.S. Patent No. 4,276,250.

31. Muni does not teach adding different amounts of nucleating agents to varying the crystallinity of a catheter in the longitudinal direction.

32. Sahatjian teaches an inflatable dilation balloon or catheter for dilatation for medical use composed of a polymer blend including a major amount of a crystalline polymer and a relatively minor amount of an additive polymer that interrupts the crystalline structure of the crystalline polymer, resulting in enhanced softness and flexibility. (Col 1., lines 23-30)

33. Satchell teaches extruding plastic tubing having axial sections of materials having different characteristics. (Col. 2, lines 42-46)

34. One of ordinary skill in the art would have recognized at the time the invention was made that it was desirable to vary the crystallinity of a catheter longitudinally as disclosed by Muni and that selective addition of a crystallization inhibitor along the length of the catheter could be used to accomplish this. The motivation would have been to increase the number of different polymers that could be utilized for catheter production beyond just those that are cold crystallizable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have combined Muni with the concept of crystallization inhibition for increased flexibility recited by Sahatjian.

35. The motivation to combine Muni and Sahatjian with Satchell would have been that "In the bio-medical field it is frequently necessary to manufacture plastic tubing having axial sections of different physical and/or chemical characteristics. For example, in the manufacture of suction catheters which are designed to be inserted through a patient's mouth and esophagus and into his lungs, it is desirable to make the forward or distal end of the catheter tube relatively soft to minimize the risk of damage to the patient's esophagus and lungs during insertion, and to make the rear or proximal end of the tube relatively stiff to facilitate insertion and positioning of the tube." (Satchell, Col. 1, lines 14-24)

36. Utilizing the extrusion method of Satchell to extrude alternating sections of polymer with and without crystallization inhibitor added would produce a catheter with the same desirable characteristics as that disclosed by Muni.

37. Regarding claims 1, 7-8, 26-29, 30,34 and 38-39: It would have been obvious to one having ordinary skill in the art at the time the invention was made to have combined Muni, Sahatjian and Satchell to produce a dilatation balloon with varying amounts of crystallization inhibitor disposed along the length of the balloon depending on the flexibility desired for the application. (Claims 1, 7-8, 26-29, 30,34 and 38-39)

38. Regarding claims 9 and 10: It would have been obvious to one having ordinary skill in the art at the time the invention was made to have disposed crystallization inhibitor in the distal waist portion of the device in order to increase the softness of the end portion of the device. (Claim 9) It would have been obvious to one having ordinary skill in the art at the time the invention was made to have not added crystallization

inhibitor to the balloon body portion of the device in order the optimize the flexibility profile of the catheter. (Claim 10)

39. Regarding claim 40: Plasticizers inhibit the crystallization of polymer materials. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized any of the crystallization inhibitors listed in claim 40 as all are well known in the art as plasticizers.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Jacobson whose telephone number is (571) 272-8905. The examiner can normally be reached on Monday-Friday 7:30 AM-5 PM EST (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, D. Lawrence Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele L. Jacobson
Examiner
Art Unit 1709

D. LAWRENCE TARAZANO
PRIMARY EXAMINER